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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



**In re the application of:** Jonathon Dinsmore

**Serial No.:** 09/163,272

**Filed:** CPA filed on May 3, 2002

(filed September 29, 1998)

**For:** *Porcine Spinal Cord Cells and Their Use in Spinal Cord Repair*

**Attorney Docket No.:** DNI-041CPA

**Group Art Unit:** 1632

**Examiner:** Anne-Marie Baker, Ph.D.

Commissioner for Patents
Washington, D.C. 20231

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on the date set forth below:

January 16, 2003
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## DECLARATION UNDER 37 C.F.R. §1.132 OF JONATHAN DINSMORE

I, Jonathan Dinsmore, a citizen of the United States of America, residing in Brookline, Massachusetts, hereby declare as follows:

1. I am presently Senior Director of Cell Transplantation Research at Diacrin, Inc. I have been working in the area of cellular transplantation for approximately 9 years. A copy of my curriculum vitae is attached as Appendix A.

2. I have carefully read the above-referenced application, including presently pending claims 1, 3-8, 10-18, 20-26, and 28-47 (attached hereto as Appendix B and C, respectively). It is my understanding that the invention set forth in these claims pertains to a composition for transplantation into a mammalian xenogeneic subject comprising isolated spinal cord cells obtained from an embryonic pig of between about 24 and about 35 days of gestation, such that treatment of spinal cord damage that would benefit from survival and integration of the spinal cord cells is obtained upon transplantation into the subject. I understand that the invention set forth in these claims further pertain to a method of treating a mammalian xenogeneic subject having spinal cord damage that would benefit from survival and integration of porcine spinal cord cells by administering to the subject a composition comprising isolated spinal cord cells obtained from an embryonic pig of between about 24 and about 35 days of gestation, such that treatment of spinal cord damage is obtained upon administration of the composition to the subject.

3. I have carefully read and understood portions of the most recent office action in the above-identified application, in particular the rejection of record of claims 1, 3-8, 10-18, 20-26, and 28-48 which have been rejected under 35 U.S.C. 112, first paragraph as set forth at pages 2-4 of the Office Action (attached as Appendix D). It is my understanding that the Examiner is taking the position that the specification does not reasonably provide enablement for methods of treating a xenogeneic subject having spinal cord damage arising as a result of a neurodegenerative disorder, a spinal cord injury, and aging.

4. I have carefully read and understood the data presented as Appendix E of this Declaration. This Appendix shows the results of transplantation of xenogeneic porcine spinal cord cells in recipients having spinal cord damage. The data shown in the table in Appendix E demonstrate that transplantation of embryonic porcine spinal cord cells into human subjects having various types of spinal cord damage, not just amyotrophic lateral sclerosis, can improve both the motor and sensory function of the subjects. The types of spinal cord damage shown to be improved by transplantation of embryonic porcine spinal cord cells include spinal cord injury resulting from trauma to both the upper (cervical) and lower (lumbar) regions of the spinal cord and transverse myelitis (TM), a neurodegenerative disorder. Results shown in Appendix E were obtained from transplant recipients who were regularly examined for improvements in their overall impairment. Each recipient showed improvement in the months following transplantation of embryonic porcine spinal cord cells, including improvements in motor and sensory functions and impairment. Evaluations of the recipients were performed according to the standard established by the American Spinal Injury Association (ASIA), which is described briefly herein (a summary of ASIA scoring is also provided in Appendix F).

Impairment was rated on a scale of A-E, where the lowest rating (A) indicates complete impairment, *i.e.*, no motor or sensory function is preserved in the sacral segments, and the highest rating (E) indicates normal motor and sensory function. Impairment improved in each recipient where impairment was evaluated. Recipient CLO-02, who had transverse myelitis, improved from an A rating to a C rating within a year of receiving transplanted porcine cells. Furthermore, recipients LDS-04 and SRL-05, who both had lumbar spinal cord injuries resulting from trauma, improved from an A rating to a B rating within the first five months of transplantation.

Motor skills were also assessed using the ASIA motor score rating system, wherein both the right and left side of the individual is examined and given a score of up

to 50 for each side, with a total potential score of 100. As shown in Appendix E, each of the transplant recipients showed an increase in their motor score rating in the months following embryonic porcine cell transplantation. For example, for recipient WDS-03, who had a cervical spinal cord injury caused by trauma, the motor score rating increased in the months following the transplantation, rising from a score of 30 to 32 by the ninth month. In another example, recipient LDS-04, who had a lumbar spinal cord injury caused by trauma, had a baseline score of 52 at the time of the transplantation and increased the score to 54 in the two months following the transplantation.

Sensory skills were also assessed using the ASIA motor score rating system, wherein both the right and left side of the individual is examined using the pin prick test and the light touch test. Based on the subject's response to each test, the subject is given a score of up to 56 for each test on each side, with a total potential score of 224. As shown in Appendix E, each of the transplant recipients showed an increase in their sensory score rating in the months following embryonic porcine cell transplantation. For example recipient LDS-04 who had a lumbar spinal cord injury resulting from trauma showed an improved sensory score of 142 to 148 in the two months following the transplantation. In another example, recipient CLO-02 who had transverse myelitis showed an improved sensory score from 158 to 189 in the twelve months following the transplantation.

Accordingly, the data presented in Appendix E demonstrate that the transplantation of xenogeneic porcine spinal cord cells can be used effectively as treatment for improving both the sensory and motor function of human subjects having spinal cord damage.

5. It is my opinion that one of ordinary skill in the art at the time the above described invention was made, having carefully read and understood the experiments presented in the specification of the above-identified application and being armed with

the knowledge available to those of ordinary skill in the art, would have recognized that the compositions and methods described therein are broadly applicable to the treatment of many types of spinal cord damage, including neurodegenerative disorders, spinal-cord injuries, and aging. The data presented in Appendix E attached hereto, further substantiate the broad applicability of the claimed compositions and methods to the treatment of spinal cord damage.

6. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

Jonathan Dinsmore

Jonathan Dinsmore

1/16/03

Date